UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

BARRY FAMILY LP, On Behalf of Itself and All Others Similarly Situated, Plaintiff, v. ALKERMES, INC., RICHARD F. POPS, ROBERT A. BREYER, DAVID A. BROECKER, MICHAEL J. LANDINE, JAMES M. FRATES and JAMES L. WRIGHT, Defendants.	No. CLASS ACTION COMPLAINT FOR VIOLATIONS OF FEDERAL SECURITIES LAWS **JURY TRIAL DEMANDED** MAGISTRATE JUDGE Dein 03 12243 RCL

Plaintiff, by its attorneys, for its Class Action Complaint, alleges the following upon personal knowledge as to itself and its own acts, and upon information and belief based upon the investigation of plaintiff's attorneys, as to all other matters. The investigation includes the thorough review and analysis of public statements, publicly filed documents of Alkermes, Inc. ("Alkermes" or the "Company"), press releases, news articles and the review and analysis of accounting rules and related literature. Plaintiff believes that further substantial evidentiary support will exist for the allegations set forth below after a reasonable opportunity for discovery.

SUMMARY OF ACTION

1. This is a securities class action on behalf of all purchasers of the common stock of Alkermes, Inc. between April 22, 1999 and July 1, 2002 (the "Class Period"), against Alkermes and certain of its officers and directors for violations of the Securities Exchange Act of 1934 (the "1934 Act").

2. Alkermes is a biopharmaceutical company focused on the development of controlled-release drug delivery technologies and their application to existing or new drug therapies. Among the drug delivery technologies defendants seek to develop are sustained-release systems based on biodegradable polymeric microspheres, including those based on Medisorb polymers.

3. To demonstrate that the Medisorb-based technology had come of age, defendants signaled, at the beginning of the Class Period, the achievement of an important milestone. Defendants announced that, despite a variety of challenges, they had succeeded in the development and scale-up of current Good Manufacturing Practices ("cGMP") production, using the Medisorb technology, of pivotal clinical lots for Risperdal Consta – an important product candidate for the treatment of schizophrenia.

4. During the Class Period, defendants assured investors of the promise of its Medisorb polymeric sustained-release delivery technology as an approach to improve the safety, tolerability and adverse effects of new or existing drugs. Defendants distinguished their sustained-release drug delivery system from oral formulations, pointing to several and certain serious concerns that were known to exist with the current tablet and oral-solution formulations, including anxiety, drowsiness, uncontrolled tremors and muscle stiffness, dizziness, constipation, nausea, upset stomach, runny nose, rash and rapid heartbeat.

5. During the Class Period, defendants further assured investors that the deal defendants made with Risperdal Consta joint venture partner JPI Pharmaceutical International ("Janssen") would be profitable to the Company, particularly since an agreement had been negotiated to secure, aside from the anticipated royalties and manufacturing payments under

previous agreements, certain guaranteed financial payments and arrangements to eliminate significant financial risks.

6. During the Class Period, defendants artificially inflated the price of Alkermes shares by issuing a series of materially false and misleading statements about the Company's New Drug Application ("NDA") for Risperdal Consta.

7. The true facts, which were known by each of the defendants during the Class Period but were concealed from the investing public, were as follows:

(a) In an attempt to decrease development expenses and speed the product to market, defendants concealed the deficient nature of the manufacturing process for Medisorb polylactide-glycolide ("PLGA") polymer used to manufacture Risperdal Consta, resulting in quality management issues and delays in the development program.

(b) In order to conceal lot-to-lot variations resulting from the manufacturing process for Medisorb polymer, defendants minimized process development and validation requirements, including the establishment of specifications and analytical tests necessary to control those variations.

(c) Significant quality issues for the manufacture of Risperdal Consta existed at the Wilmington, Ohio facility, impacting the ability of the Company to meet clinical development timelines for Risperdal Consta.

(d) In order to avoid disclosure of the serious deficiencies of the Medisorb manufacturing process, particularly the lot-to-lot variation in molecular weight for Medisorb polymer, and in order to find a way to fix the desired molecular weight of the Risperdal Consta finished drug product, defendants patented a method to degrade the finished product to the

desired molecular weight.

(e) Defendants' revenue projections for Risperdal Consta were grossly inflated based on defendants' concealment of the fact that Risperdal's adverse effects and safety or tolerability issues worsen when Risperdal is formulated using Medisorb technology and used as intended.

(f) Defendants concealed that due to the combined effect of the financial agreements reached with its joint venture partner, Janssen, Risperdal Consta would not be profitable unless it achieved the high end of sales projections, an unlikely outcome because of the worsening of Risperdal's adverse effects and safety or tolerability issues when the drug is formulated using Medisorb technology and used as intended.

(g) The serious safety concerns for Risperdal "oral" and Risperdal Consta "depot" products, such as cerebrovascular effects in elderly patients, extrapyramidal symptoms, QT interval prolongation and diabetes, which were detected in clinical trials that went unreported to worldwide regulatory authorities for long periods, in some cases for studies completed well before the beginning of the Class Period, were negatively impacting the regulatory review process.

(h) For one or more reasons related to the known but unmet manufacturing, safety or efficacy requirements for the drug, the NDA for Risperdal Consta would not be approved on July 1, 2002.

(I) The failure to disclose the defective nature of the Risperdal Consta chemical and manufacturing controls, clinical program, safety and other issues preventing the Company from realizing product approval would prevent investors from learning the extent of the

misrepresentations made to them during the Class Period.

8. As a result of the defendants' false statements, Alkermes stock traded at inflated prices during the Class Period, increasing to as high as $70.06 on February 16, 2000, whereby the Company sold $200 million worth of its own securities.[1]

9. On July 1, 2002, defendants announced the receipt of a non-approvable letter for Risperdal Consta. As a result of this announcement, Alkermes' stock price dropped precipitously over the next two days to a low of $4.04, or a loss of 93% from its Class Period high of $98 per share, on total volume of 29 million shares.

JURISDICTION AND VENUE

10. Jurisdiction is conferred by §27 of the 1934 Act. The claims asserted herein arise under §§10(b) and 20(a) of the 1934 Act and Rule 10b-5. Venue is proper in this District pursuant to §27 of the 1934 Act as many of the false and misleading statements were made in or issued from this District. The Company's principal executive offices are in Cambridge, Massachusetts, where the day-to-day operations of the Company are directed and managed.

THE PARTIES

11. Plaintiff Barry Family LP purchased Alkermes common stock as described in the attached certification and was damaged thereby.

12. Defendant Alkermes is a biopharmaceutical company focused on the discovery, development and commercialization of new small molecule drugs for the treatment of cardiovascular diseases. During the Class Period, defendants caused the Company to sell $200

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[1]All share and per-share amounts have been adjusted for Alkermes' 2-for-1 stock split in May 2000.

million worth of its securities.

13. Defendant Richard F. Pops ("Pops") was Chairman and CEO of Alkermes. During the Class Period, Pops sold 663,312 of his Alkermes shares, for net proceeds of $20.3 million.

14. Defendant Robert A. Breyer ("Breyer") was President of Alkermes until December 2001 and is a director of the Company. During the Class Period, Breyer sold 522,375 of his Alkermes shares, for net proceeds of $14.7 million.

15. Defendant David A. Broecker ("Broecker") was Chief Operating Officer of Alkermes.

16. Defendant Michael J. Landine ("Landine") was Vice President of Corporate Development and a former CFO of Alkermes. During the Class Period, Landine sold 183,500 of his Alkermes shares, for net proceeds of $5.4 million.

17. Defendant James M. Frates ("Frates") was Vice President, Chief Financial Officer and Treasurer of Alkermes. Defendant Frates managed Finance, Intellectual Property, Investor Relations and Human Resources. In addition, he oversaw the pending acquisition of Reliant Pharmaceuticals, as well as Alkermes' $200 million convertible bond issue. During the Class Period, Frates sold 86,000 of his Alkermes shares, for net proceeds of $2.8 million.

18. Defendant James L. Wright ("Wright") was Senior Vice President, Research and Development of Alkermes. During the Class Period, Wright sold 5,000 of his Alkermes shares, for a net proceeds of $164,000.

19. The individuals named as defendants in ¶¶13-18 are referred to herein as the "Individual Defendants." The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Alkermes' quarterly

reports, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. Each defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them but not to the public, each of these defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations which were being made were then materially false and misleading. The Individual Defendants are liable for the false statements pleaded herein at ¶¶34, 39, 41, 48, 50, 52, 57, 61 and 63, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

SCIENTER

20. In addition to the above-described involvement, each Individual Defendant had knowledge of Alkermes' problems and was motivated to conceal such problems. Landine, as CFO, was responsible for financial reporting and communications with the market. Many of the internal reports showing Alkermes' forecasted and actual growth were prepared by the finance department under Landine's direction. Defendant Pops, as CEO and Chairman, was responsible for press releases issued by the Company. Wright, as Vice President of Research and Development, was responsible for development and manufacturing readiness. Each Individual Defendant sought to demonstrate that he could lead the Company successfully and generate the growth expected by the market.

FRAUDULENT SCHEME AND COURSE OF BUSINESS

21. Each defendant is liable for (I) making false statements, or (ii) failing to disclose adverse facts known to him about Alkermes. Defendants' fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Alkermes common stock was a success, as it (I) deceived the investing public regarding Alkermes' prospects and business; (ii) artificially inflated the prices of Alkermes' common stock; (iii) allowed defendants to sell $200 million worth of Alkermes securities at artificially inflated prices; (iv) allowed Alkermes to enter into an agreement to complete its acquisition of Reliant Pharmaceuticals using Alkermes shares at artificially inflated prices; (v) allowed several defendants to sell their own shares at artificially inflated prices for insider trading proceeds of over $43 million; and (vi) caused plaintiff and other members of the Class to purchase Alkermes common stock at inflated prices.

BACKGROUND AND OVERVIEW

About the Company and the Drug

22. Defendant Alkermes is a biopharmaceutical company focused on the development of controlled release drug delivery technologies and their application to existing or new drug therapies. The Company's NDA for Risperdal Consta (depot product, depot formulation) for the treatment of schizophrenia has been filed at the FDA. Risperdal (Risperidone) belongs to a class of compounds referred to as atypical antipsychotics, used in the treatment of schizophrenia. If approved by the FDA, Risperdal Consta would represent the first example of a sustained release or "depot" formulation for biweekly administration, to mitigate patient compliance issues.

23. The Risperdal Consta development effort is the result of a partnership between Medisorb Technologies International L.P. ("MTI") and Janssen. MTI entered into a development

agreement with Janssen on or about December 23, 1993. Alkermes acquired the Risperdal Consta development program through the acquisition of MTI by its Alkermes Controlled Therapeutics Inc. II ("ACT II") subsidiary in 1996. The original development agreement was followed by two licensing agreements signed on or about February 21, 1996. The original development agreement was then amended on or about March 8, 1997 ("Second Amendment"). A definitive Manufacturing and Supply Agreement ("Mfg. Agreement") for a depot formulation of Risperidone was established on or about August 6, 1997. Other amendments and agreements occurred between the parties during the Class Period.

24. Within the Mfg. Agreement of 1997 are certain terms between the parties to address the responsibilities of the parties, including forecasting for the development and commercial production of Risperidone a "Manufacturing Readiness Plan" by which Alkermes would commit such resources and undertake such maintenance and training programs as needed to keep ACT II manufacturing facilities in a state of readiness for commercial manufacture of Risperidone. The 1997 Mfg. Agreement also covers quality and regulatory considerations, including the preparation and filing of a facilities Drug Master File ("DMF") with respect to the facilities where ACT II would manufacture the product and polymers.

25. The submission of a DMF is not required by law. A DMF is sometimes submitted to the FDA as a tool to protect confidential and detailed information about facilities, processes, or articles used in the manufacturing, processing, purchasing, and storing of drug products. DMFs allow a party other than the DMF holder to reference materials without disclosing to that party the contents of the file. The result is the maintenance of the confidentiality of the contents to the DMF holder. The FDA will typically not review the substantive elements of the DMF until it is ready to

review the IND, NDA or other application referencing the DMF.

26. Schizophrenia is a chronic, severe and disabling brain disease. Deterioration of brain matter can sometimes be detected or measured, and is particularly profound in children with early onset of the disease, affecting verbal memory, attention, reasoning, aggression and meaningful speech. According to the National Institute of Mental Health, approximately 1% of the world population suffers from schizophrenia in any given year. This suggests that as many as 2 million people in the United States are affected. Schizophenia can be difficult to diagnose, but is usually manifested in a variety of so-called positive and negative symptoms. Positive symptoms are usually manifested as hallucinations or delusions that distort a person's sense of reality, often leading to paranoia. Negative symptoms are usually manifested as forms of isolation or withdrawal accompanied by poor personal hygiene or general lack of motivation. Combinations of positive and negative symptoms are possible, resulting in a diagnosis of manic or bipolar disorders.

27. The goal of a successful drug to treat schizophrenia is to inhibit and eliminate the mental, emotional, and behavioral disturbances associated with the disorder, with minimal side effects. Risperidone (Risperdal, 3-[2-[4-(6-Fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl] - 6,7,8,9-tetrahydro-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one) is a so-called "atypical" antipsychotic, a term reserved for the subclass of drugs having prominent antiserotonergic (5-HT2) as well as antidopaminergic (D2) and antihistaminic (H1) activities.

28. Risperdal Consta is a white powder made from Risperidone and 7525 DL JN1 poly-(d,l-lactide-co-glycolide) Medisorb polymer. The 7525 designation means that the polymer is composed of lactide (A) and glycolide (B) units in a 75/25 ratio, in a random (unknown) sequence

of "A" and "B" units. Polymers composed exclusively of A or B units have much slower rates of hydrolysis – decomposition with water – than polymers composed of mixtures of A and B units. Risperdal Consta is made by a combination of patented and proprietary processes that dissolve the Medisorb polymer, mix into it the Risperidone drug, and finally precipitate the polymer in the form of "microspheres." The microspheres are formed and processed in a sterile environment, whereby a known amount of powder is deposited in clean sterile vials. Critical to the process are methods to obtain the proper particle size of the microspheres and the uniform distribution of the drug in the polymer. Biweekly depot dosage forms currently available ex-U.S. include 25 mg, 37.5 mg and 50 mg. The 25 mg dosage form appears to be equivalent to a 2 mg oral dose.

29. According to ex-U.S. consumer information for the drug, Risperdal Consta is to be stored and used in the following manner: First, vials containing Risperdal Consta should be refrigerated at all times prior to use. To administer Risperdal Consta, the powder is diluted with an aqueous injection vehicle using a needle and syringe. The contents of the vial are shaken until a suspension is formed, appearing thick and milky in color. The entire contents of the vial is withdrawn, an appropriate needle is employed, air bubbles removed and, by application of proper technique, the entire contents of the syringe are injected intramuscularly into the buttock of the patient.

30. The release of Risperdal from the Risperdal Consta drug product may be described by an "in vivo release profile," the manner by which the drug entrapped in the Medisorb polymer matrix is released once the microspheres have been injected into the patient. For example, if the release profile demonstrates a "burst effect," releasing too much of the drug into the patient within a 24-hour period, the patient might experience an extremely high dose of the drug, followed by a

lower linear release over time. Alternatively, the release profile could be sigmoidal in nature, characterized by an initial lag in the release of the drug from the Medisorb polymer matrix, followed by a steep intermediate release phase, and ending in a flat final release phase. The defendants have a patented technology that they may employ to control the in vivo release profile as a percent of total drug released from the microparticles (microspheres), as determined at specific timepoints.

Safety of Risperdal Consta

31. The degree to which advantages with sustained or extended release drug formulations are realized is determined in part by safety considerations, including the ability to discontinue patient treatment when serious drug-related side effects are observed or when other critical medications capable of drug-drug interactions must be administered.

32. Alkermes reassured investors by explaining the advantages of and experience it has with its ProLease and Medisorb sustained-release drug delivery technologies on its Web site:

> ProLease® and Medisorb® Injectable Sustained-Release Drug Delivery Systems Alkermes® has developed two uniquely complementary platforms for drug delivery: ProLease and Medisorb injectable sustained-release technologies for both small and macromolecules. With release profiles lasting from days to months, each is designed to eliminate the need for frequent dosing. Each has the potential to:
>
> - Improve patient compliance and convenience by reducing dosing frequency
> - Improve safety and tolerability
> - Reduce adverse effects associated with peak/trough levels of other (oral) dosage forms
> - Commercialize products that would otherwise not be viable because of delivery or economic considerations

- Optimize product life cycle management

The advantages are clear.

> Each technology supports a broad array of applications and offers customizable release profiles lasting from days to months.
>
> Alkermes has refined outstanding expertise in the kinetics of controlled release by generating predictable in vivo performances and clinically proven formulations.
>
> With established commercial manufacturing facilities and all encompassing development infrastructure, Alkermes solidifies its position as a market leader in injectable sustained-release.
>
> Alkermes' commitment to innovation brings product concepts to realization.

33. When the oral dosage form can cease to be administered or the dosage unit can be readily removed from the patient, as in the case of a transdermal patch, safety issues can be more readily addressed. When the formulation is designed as an implanted biweekly sustained-release dosage form, utilizing Medisorb polymer for sustained release of Risperdal, a drug known to defendants as having significant and serious side effects, potentially life-threatening safety issues could result from defendants' product design.

DEFENDANTS' FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD

34. On April 22, 1999, defendants issued a press release entitled "Alkermes and Janssen Pharmaceutica to Proceed into Phase III Clinical Trials of Sustained Release Formulation of Anti-Psychotic Drug Risperdal®." The press release stated in part:

> Alkermes, Inc. announced today that Janssen Research Foundation, a division of Janssen Pharmaceutica, will proceed into Phase III clinical trials of an IM injectable sustained release formulation of the anti-psychotic drug RISPERDAL® (risperidone). The product candidate is based on Alkermes' Medisorb® drug

> delivery system and is designed to provide patients with prolonged therapeutic benefit from a single administration. The decision to proceed into Phase III clinical trials follows the successful completion by Janssen of Phase I and Phase II clinical trials of the product candidate and the completion by Alkermes of scale-up and Phase III manufacturing activities at the expected commercial scale.
>
> ***"This is an important milestone in the development of this product candidate and of our Medisorb drug delivery technology," said Richard F. Pops, Chief Executive Officer of Alkermes. "We have moved rapidly in the development and scale-up of this product candidate with our partners at Janssen Pharmaceutical. We look forward to the next phase of product development."***

(emphasis added).

35. Defendants concealed the fact that the Medisorb facilities comprised two parts: research and development operations in the "Blue Ash" facility located at 6954 Cornell Road in Cincinnati, Ohio, and manufacturing facilities located approximately 35 miles north on Olinger Circle in Wilmington, Ohio.

36. ***While defendant Pops announced the production of manufacturing lots at commercial scale, the defendants concealed that the Wilmington facility was wholly unable to commence or maintain commercial scale operations for cGMP manufacture of Risperdal Consta or any other drug product.*** As of the April 22, 1999 press release, the only DMF in existence, established on March 15, 1990, was for the manufacture of Medisorb polymer at the Blue Ash facility in Cincinnati, Ohio. No such document had ever been filed for the Wilmington, Ohio facilities for the production of Medisorb injectable sustained-release drug delivery systems. Nor have defendants ever sustained a successful FDA pre-approval inspection in connection with the manufacture of any commercial drug products based on Medisorb sustained-release technology or in the Wilmington facilities.

37. Defendants also concealed quality issues with the 7525 DL JN1 poly-(d,l-lactide-

co-glycolide) Medisorb polymer used in the production of Risperdal Consta manufacturing lots. Defendants knew that a uniform process for manufacture of polymer, achieving control over important quality parameters such as molecular weight, was critical. The decision not to routinely conduct tests for molecular weight on its Medisorb cGMP polymer lots concealed the fact that Medisorb polymer production methods resulted in molecular weights with lot-to-lot variations unacceptably wide for use in production of sustained-release drug delivery systems. Defendants knew at all times during the Class Period that: (I) polymer molecular weight affects drug release characteristics; (ii) the molecular weight of a polymer influences the biodegradation rate of the polymer; and (iii) polymer lot-to-lot variations can influence the in vitro and in vivo release profiles of the drug within a polymer matrix. In addition to the deficient state of the Wilmington manufacturing facilities, the April 22, 1999 press release failed to disclose the inadequate nature of the manufacturing process and controls for cGMP manufacture of Medisorb polymer lots that substantially contributed to the quality issues in the manufacture of Risperdal Consta research and clinical supplies during the Class Period.

38. In January 2000, defendant Breyer sold 200,000 Alkermes shares, defendant Frates sold 8,000 Alkermes shares, defendant Landine sold 99,000 Alkermes shares and defendant Pops sold 350,000 Alkermes shares at prices between $24.50 and $25.50 per share.

39. On February 16, 2000, at a time when the Company's shares were already trading at artificially inflated prices, the Company issued a press release entitled "Alkermes Announces Placement of $200 Million in Convertible Subordinated Notes." The press release stated in part:

> Alkermes today announced the private placement of $200 million aggregate principal amount of its 3¾% Convertible Subordinated Notes due 2007. The offering, which was made through initial purchasers to qualified institutional

> buyers under Rule 144A under the Securities Act of 1933, is expected to close on February 18, 2000. Alkermes has also granted the initial purchasers of the notes an option to purchase up to an additional $50 million in principal amount of the notes. The notes are convertible into common stock of Alkermes at a conversion price of $135.50 per share, subject to adjustment in certain circumstances. Alkermes has agreed to file a registration statement for the resale of the notes and the common stock issuable upon conversion of the notes within 60 days after the closing of the offering.

40. News of the success of this badly needed financing reassured investors that the company's products were viable and that the investment banking community stood behind the Company's science. Most importantly, as a result of this financial announcement, defendants convinced investors that the Company's success was assured, as shares spiked nearly 90% in value in the days that followed the announcement.

41. On May 19, 2000, defendants caused Application Ser. No. 09,575,075 to be filed with the U.S. Patent and Trademark Office for the grant of a patent entitled "Method for Preparing Microparticles Having a Selected Polymer Molecular Weight." Among the details describing the preferred embodiments of the invention was the following statement explaining the key use of the method:

> The methods of the present invention control the hold time and temperature of a polymer solution in order to control the molecular weight of the polymer in the finished microparticle product. In this manner, the methods of the present invention advantageously allow a selected polymer molecular weight to be achieved from a variety of starting material molecular weights. Alternatively, microparticle products of varying polymer molecular weights can be produced using the same molecular weight starting material. Thus, a range of products can be made from the same starting materials, thereby eliminating the need to reformulate the finished product to achieve the desired molecular weight of the polymer in the finished product.

42. By seeking the approval of the patent application on made on May 19, 2000,

defendants sought to demonstrate expertise in the field and the capacity to create valuable intellectual property, while concealing a desperate need to identify product manufacturing methods to "fix" the quality issues relating to wide variations in the quality of Medisorb polymer required for the manufacture of Risperdal Consta.

43. Defendants knew that Medisorb PLGA polymers are actually composed of random (unknown) sequences of lactide (A) and glycolide (B) units, resulting in polymer strand regions with interspersed block (AB... AA... or BB...) sequences of unknown length. Defendants knew that degradation rates of PLGA polymers in solution have markedly different degradation rates, on the order of weeks or months, depending on the lactide/glycolide ratio, a fact critical to the polymer selection process and to the performance of a Medisorb sustained release PLGA based drug delivery system in vivo. Yet, despite defendants' knowledge of the critical nature of the lactide/glycolide ratio on the performance of Medisorb technology, defendants concealed the impact of the erosion process in the May 19, 2000 patent application, when applied to 75/25 Medisorb PLGA polymer having molecular weights ranging from 92 to 230 kiloDaltons (kD), on the lactide/glycolide ratio.

44. Defendants' use of a manufacturing scheme that included either or both patented methods, first to "erode" or "degrade" the Medisorb polymer in an organic solution of the polymer containing Risperdal, and secondly to control the "burst effect," would further complicate defendants' efforts to achieve a cGMP compliant Risperdal Consta manufacturing process. The reason defendants sought new patented and proprietary processes that would actually complicate the Risperdal Consta manufacturing process was so that they could continue their concealment of quality issues relating to variation in the manufacturing process for the Medisorb polymer.

Defendants sought these complications even though they realized that they would create significant obstacles in achieving a controlled manufacturing process capable of validation, a key requirement for FDA inspection activities necessary to demonstrate readiness for manufacture of the product in the Wilmington facility.

45. In July 2000, defendant Breyer sold 75,000 Alkermes shares, defendant Frates sold 30,000 Alkermes shares, defendant Landine sold 40,000 Alkermes shares and defendant Pops sold 175,000 Alkermes shares at prices between $44.09 and $45.61 per share.

46. In September 2000, defendants' joint venture partner Janssen caused to be published a Review Article entitled "A Risk-Benefit Assessment of Risperidone for the Treatment of Behavioural and Psychological Symptoms in Dementia" ("Risk Assessment"). The article signaled the acceptability of the safety and efficacy profile of the drug for the treatment of dementia in the elderly. While the article was intended to disclose serious Risperdal side effects as part of a risk-benefit assessment, it actually concealed serious adverse cerebrovascular side effects ("CVAEs") in the elderly, contained in one or more Janssen studies cited as references to the article.

47. From January 2001 through July 2001, defendant Breyer sold 135, 000 Alkermes shares, defendant Frates sold 20,000 Alkermes shares, defendant Landine sold 18,000 Alkermes shares, defendant Pops sold 55,000 Alkermes shares and defendant Wright sold 5,000 Alkermes shares at prices between $22.00 and $34.65 per share.

48. On or about August 1, 2001, defendants executed an Addendum to the Mfg. Agreement of 1997 ("Wilmington Facility Agreement"). The intent of this agreement was to recognize and remedy the fact that the Wilmington manufacturing facilities for the Risperdal drug

product were inadequate and not ready to undertake the cGMP manufacture of Risperdal Consta based on increased sales forecasts, once the product would be approved:

> ADDENDUM TO MANUFACTURING AND SUPPLY AGREEMENT
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> This Addendum to Manufacturing and Supply Agreement (this "Addendum"), dated as of the 1st day of August, 2001 (the "Effective Date") is by and between JPI PHARMACEUTICAL INTERNATIONAL, a division of Cilag AG International Zug, a company duly organized and existing under the laws of Switzerland, having its principal office in CH-6300 Zug, Kollerstrasse 38, Switzerland ("JPI") and JANSSEN PHARMACEUTICAL Inc., 1125 Trenton-Harbourton Road, Titusville, NJ 08560, USA ("Janssen US" and, together with JPI, "Janssen") on the one hand and Alkermes Controlled Therapeutics Inc. II, a company organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal office at 64 Sidney Street, Cambridge MA 02139-4136, USA ("ACTII") on the other hand.
>
> WHEREAS, Janssen and ACTII have been collaborating for the development of a Risperidone depot formulation incorporating ACTII's proprietary technology concerning bioabsorbable polymer technologies and have entered into a Development Agreement and two License Agreements related thereto; and
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> WHEREAS, Janssen and ACTII entered into that certain Manufacturing and Supply Agreement, dated August 6, 1997 (the "Supply Agreement"), with respect to the commercial manufacture and supply of such Risperidone depot formulation to Janssen; and
>
> WHEREAS, Janssen and ACTII desire to enter into this Addendum regarding the expansion of ACTII's manufacturing facilities, and the financial responsibilities of each of the parties in connection with such expansion, in order to support the increased sales forecasts for such Risperidone depot formulation; and
>
> WHEREAS, Janssen and ACTII further desire to enter into this Addendum to formally provide for a collaborative effort to develop the manufacturing facility and commercial supply of Product.

49. Between August 1, 2001 and August 17, 2001, defendant Landine sold 4,000 Alkermes shares, defendant Frates sold 4,000 Alkermes shares, defendant Pops sold 12,500

Alkermes shares and defendant Breyer sold 12,000 Alkermes shares at prices between $26.46 and $27.92 per share.

50. On September 4, 2001, the Company issued a press release entitled "New Drug Application for First Injectable, Long-Acting Atypical Antipsychotic Submitted to FDA." The press release stated in part:

> A new drug application for a long-acting injectable formulation of Risperdal® (risperidone)* has been filed with the Food and Drug Administration by Janssen Pharmaceutical Products, LP, and similar filings are now being submitted with health authorities worldwide. If approved, it would be the first atypical antipsychotic medication available in a formulation suitable for long-term use that requires administration just once every two weeks, instead of daily doses.
>
> Using proprietary Medisorb® technology developed by Alkermes, Inc., the new formulation encapsulates risperidone in "microspheres" made of a biodegradable polymer, which is injected into the muscle. Laboratory and clinical research has shown that the microspheres gradually degrade at a set rate designed to provide consistent levels of the drug in the bloodstream. The polymer from which the microspheres are made breaks down into two naturally occurring compounds that are then eliminated by the body. ***Alkermes is scheduled to manufacture this long-acting formulation of Risperdal pending regulatory approval.***
>
> Risperdal tablets, first introduced in the United States in 1994, have become the most widely prescribed atypical antipsychotic in the world, and the most commonly used antipsychotic of any type in the United States. It is indicated for the management of psychotic symptoms, such as those associated with schizophrenia – a brain disorder that affects about 1-2 percent of the world's population (including 2 million Americans). Older, conventional antipsychotics have been available in longer-acting, injectable formulations, which have been associated with significant side effects.
>
> In its current tablet and oral-solution formulations, Risperdal has been shown in clinical trials to be effective and generally well tolerated. However, as with all antipsychotic medications, it was associated with side effects. In two controlled trials, adverse events that occurred in at least 5 percent of patients receiving Risperdal and were experienced at least twice as often as those taking placebo were anxiety, drowsiness, extra pyramidal symptoms (uncontrolled tremors and muscle stiffness), dizziness, constipation, nausea, dyspepsia (upset